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09/806,840	07/25/2001	Robin Arthur Ellis Carr	PU3565USW	7700

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY  
GLAXOSMITHKLINE  
FIVE MOORE DR., PO BOX 13398  
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/806,840

Applicant(s)

CARR ET AL.

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/14/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,10,12-31 and 52-58 is/are pending in the application.
- 4a) Of the above claim(s) 14-16,24-26 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,10,12,13,17-23,27 and 52-58 is/are rejected.
- 7) ☒ Claim(s) 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 3-6, 10, 12-31 and 52-58 are pending. Claims 52-58 were added in the amendment to the claims, filed 10/14/04. Claims 14-16, 24-26 and 28-31 remain withdrawn. Claims 1, 3-6, 10, 12, 13, 17-23, 27 and 52-58 are examined.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/04 has been entered.

### ***Election/Restrictions***

3. Claims 14-16, 24-26 and 28-31 remain withdrawn from consideration by the examiner, as being drawn to non-elected species, there being no allowable generic claim. Claims 21, 22, 23, 55 and 56 are considered to the extent they are drawn to a first cleavage site cleavable by photochemical cleavage, a second cleavage site cleavable under acid conditions, according to applicant's election of species, filed 3/14/03.

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***Priority***

4. The instant application is a 371 of PCT/GB99/03286, filed 10/5/1999; and claims foreign priority of United Kingdom GB9821655.9, filed 10/5/1998.

***Specification***

5. An amendment to the specification at p. 4, line 24, identifying particular amino acid sequences by SEQ ID No., remains required under the nucleotide and amino acid sequence rules, as set forth in the previous Office action, mailed 7/14/2004, which in turn maintains the instant requirement, as set forth in the Office action, mailed 10/16/2003.

***Claim Objections***

6. Claim 57 is objected to because of the following informalities: Claim 57 depends from itself. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

***Withdrawn rejections***

7. The rejection of claims 1, 3-6, 10, 12, 13, 17-23 and 27 are rejected under 35 U.S.C. 112, second paragraph in the previous Office action are withdrawn in view of applicant's amendments to claims 1, 5, 18 and 22.

***New Rejections***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1, 3-6, 10, 12, 13, 17-23, 27 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 52 recites the language "a sensitising group G in masked form" renders the claims indefinite. The term "sensitising" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of "sensitising", and one of skill in the art would not be reasonably apprised of the metes and bounds of the invention as claimed. Also it is unclear as to whether "a sensitising group G in masked form" is or is not a "sensitising group", so that one of skill in the art would not be reasonably apprised of the metes and bounds of the invention as claimed. Furthermore, it is unclear as to what it is that is being sensitized by the sensitising group.

Claims 21 and 52 appears to recite an improper Markush group because it is not clear whether thermal, photochemical and enzymatic cleavage, and/or the second cleavage site are part of the group.

***Claim Rejections - 35 USC § 112, First Paragraph***

9. Claims 1, 3-6, 10, 12, 13, 17-23, 27 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

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This rejection maintains the final rejection of claims 1, 3-6, 10, 12, 13, 17-23 and 27, as set forth in the previous Office action, mailed 7/14/2004, which in turn maintains the rejection of claims 1-13, 17-23 and 27, as set forth in the Office action, mailed 10/16/2003.

*Response to Arguments*

The claims are drawn to a chemical construct for use in solid phase synthesis comprising: a solid support Q having linked thereto via a connecting group Y a substrate R; the connecting group Y having first and second cleavage sites which are orthogonally and selectively cleavable; the second cleavage site being selectively cleavable to release the substrate; and the first cleavage site being located at a position between the second cleavage site and the solid support and being selectively cleavable to release a fragment Fr comprising the substrate and at least a portion of the connecting group Y; and a moiety comprising a sensitizing G in masked form at the first cleavage site wherein the chemical fragment Fr contains a means for imparting a characteristic signature to the mass spectrum of the fragment.

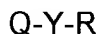
Applicant argues that the claimed subject matter is directed to combinations of elements in a new and nonobvious manner and that numerous examples of each element were known to those of ordinary skill in the art at the time the application was filed. In such a case, applicant argues, the functional or partially functional description of a group has long been approved. See, e.g., *In re Johnson*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977) (approving claim recitation in claims for a polyether composed of recurring units, with one unit having electron withdrawing groups substituted thereon,

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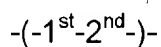
the electron withdrawing groups having a sigma value "sufficient to activate a halogen atom"). As set forth in the recent written description guidelines "The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 USC §112, ¶1, for lack of adequate written description." Federal Register, Vol. 66, pg 1105 (Jan. 5, 2001).

Applicant's arguments filed 10/14/04 have been fully considered but they are not persuasive because the instant specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." See Vas-Cath Inc. v. Mahurkar, 19 USPQ 2d 1111, 1116.

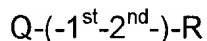
The claims are drawn to a construct comprising a solid support, Q, linked via a connecting group, Y, to a substrate R. Therefore the construct has the structure:



The connecting group, Y, comprises a first and second cleavage site. Therefore Y has the structure:



The claimed construct therefore has the structure:



The so-called "sensitising Group G in a masked form" does not appear in this formula for the claimed invention, because the claimed construct is in the uncleaved form. The examiner respectfully submits that the recitation of "sensitising Group G in a masked form" is tantamount to requiring the recognition of a sensitizing group that is not actually a sensitizing group. As such, this language does not serve to structurally limit

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the claimed construct. One of skill in the art would not be able to envision the full genus of "masked" sensitising groups, because the specification does not describe a common structure that distinguishes sensitising groups in a masked form such that the skilled practitioner would recognize whether a given molecular group could be unmasked to yield a sensitising group.

The claim does not require that the sensitising group be unmasked as a necessary consequence of cleaving the first cleavage site. The examiner respectfully submits that the claimed limitation of a masked sensitising group would encompass any group that could be modified to produce a sensitising group. Thus one of skill in the art would not have notice of, or be able to recognize what groups are or are not encompassed by the claims, given the inadequacy of specification in describing the full scope of sensitising groups "in a masked form."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3-6, 10, 12, 13, 17-23, 27 and 52-58 are rejected under 35

U.S.C. 102(e) as being anticipated by Geysen et al. (US 6,475,807).

The claims are drawn to a chemical construct for use in solid phase synthesis comprising: a solid support Q having linked thereto via a connecting group Y a substrate



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R; the connecting group Y having first and second cleavage sites which are orthogonally and selectively cleavable; the second cleavage site being selectively cleavable to release the substrate; and the first cleavage site being located at a position between the second cleavage site and the solid support and being selectively cleavable to release a fragment Fr comprising the substrate and at least a portion of the connecting group Y; and a moiety comprising a sensitizing G in masked form on the chemical fragment Fr at the first cleavage site wherein the chemical fragment Fr contains a means for imparting a characteristic signature to the mass spectrum of the fragment.

Geysen et al., throughout the patent, and especially at col. 5, lines 51-55, and Figure 111-132, disclose spectra representing the decoding of a parallel synthesis of a library on encoded resin beads, using a dual linker approach in which a first linker was a photocleavable linker and a second linker was a Knorr linker, and absent evidence to the contrary, was cleavable under acid conditions; col. 9, lines 1-28 teach cleavage of a link connected to a Ligand, wherein the Links have been doped with isotopes (including  $^{14}\text{N}$ ) to provide isotope spectra distinguishable by mass spectrometry (MS); at col. 12, line 8-col. 23, line 36, discloses cleavage between  $^{14}\text{NH}$  and CO; and disclose a scheme whereby a Link 2 is cleaved in order to determine the molecular weight of a Ligand, and where Link 1 is cleaved to enable identification of a Code block, which determines the identification of a first pool monomer; at col. 15, lines 10-35, teach a construct ("Encoding Example E") that is a resin bead-Link 1-Code-Link 2-Ligand; at col. 27-col. 28, teach cleavage of a construct comprising a substrate-NH-CO- to release

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NH<sub>2</sub>-CO- from the substrate and thus generate a terminal amine (taken to read on a sensitising group); at example 5, "Encoding Using Four Possible Diastereomers of Lin 1, Code 2, and Link 2", disclose a construct substrate-NH-CO- that is linked to a Ligand, (compare to aforementioned col. 15, "Encoding Example E"), which reads upon the claimed construct, wherein the Ligand is R, and the substrate-NH-CO- is a sensitising group in masked form at a first cleavage site, which upon cleavage would generate a terminal amine (taken to read on a sensitising group G); and at col. 63, line 18-col. 64, line 37, disclose a construct comprising a resin bead, code, Ligand and Knorr linkers (taken to read upon a Rink linker, as in claims 58).

### ***Claim Rejections - 35 USC § 102/103***

11. The rejection of claims 1, 3-6, 10, 12, 13, 17-23 and 27 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(1) as obvious over Carrasco et al. (Tet. Lett. 1997; on PTO-1449), is withdrawn in view of applicant's arguments.

### ***Conclusion***

12. Claims 1, 3-6, 10, 12, 13, 17-23, 27 and 52-58 are rejected.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PADMASHRI PONNUR  
PRIMARY EXAMINER

Mark Shibuya  
Examiner  
Art Unit 1639

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